8. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: _____

Applicant Information:

Date Prepared: July 12, 2013

Name: Osprey Medical
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Minnetonka, MN 55343
Phone: 651-270-0572
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AUG 15 2013

Contact Person: Jill Munsinger
Phone Number: 651-270-0572
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Device Information:

Trade Name	Common Name	Classification Name	Class
AVERT Contrast Modulation System	Angiographic Injector	Angiographic Injector	Class II

Predicate Devices:

The Osprey Medical AVERT Contrast Modulation System System is substantially equivalent in intended use and/or method of operation and technical aspects to the following predicate devices:

Device	Reference 510(k) Number	Indication for Use
Acist Angiographic Injection System	K993774, K991103, K000013, and K052744	...intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures
Medline Angiographic Control Syringe	K093830	An angiographic syringe is a device that consists of a syringe which is used to inject contrast material into the heart, great vessels, and coronary arteries during angiographic or CT procedures.

Device Description:
The Osprey Medical AVERT Contrast Modulation System (AVERT System) consists of a Linear Slide Apparatus, Pressure Dampening Plates, and a Wheeled Stand. The non-sterile, reusable stainless steel dampening plates are attached to a non-sterile, reusable aluminum linear slide, positioned above a 6 cc syringe. The plates apply a constant force (using gravity) on the 6 cc syringe plunger acting as pressure dampener. The number of plates can be changed depending on the injection requirements. The Linear Slide Apparatus is attached to the Wheeled Stand, near the patient outside of the sterile field. The AVERT System is used in conjunction with standard disposable, sterile, off-the-shelf items including a 6 cc syringe, a 4-way stopcock, and an extension line that are provided in a Convenience Kit with the system (CK-100).

Intended Use:
The Osprey Medical AVERT Contrast Modulation System is intended to be used for the controlled infusion of radiopaque Iodixanol 270 mg/ml contrast media for angiographic procedures.

Comparison to Predicate Device(s):
The design of the AVERT System is comparable to the Acist Angiographic Injection System and the Medline Angiographic Control Syringe. The indication for use statement of the Acist Angiographic Injection System and the AVERT System are similar with the AVERT System having a more specific indication of contrast media type. The indication for use statement of the Medline Angiographic Control Syringe is similar in intention to the AVERT System. The Medline indication relies on the user's ability to inject fluid to control the infusion. While this is different from the AVERT System, it is not considered a critical different in that they are both designed to inject materials into blood vessels/arteries.

The AVERT System is manually adjusted via addition/subtraction of plates to divert injection pressure and control infusion. Whereas the Acist system is a powered injector adjusted via the user interface and the Medlin syringe is manually controlled.

Performance Data:
The Osprey Medical AVERT System has been evaluated using the following *in vitro* bench testing to confirm the performance characteristics:

- Flow Rate
- Peak Pressure Reduction
- Contrast Reduction
- Flow Rate Adjustability
- Mechanical Cycle Testing

All test results demonstrated the materials, manufacturing processes, and design of the Osprey Medical AVERT System met the established performance criteria, will perform as intended and in a manner that is substantially equivalent to the predicated devices cited.

Summary:
Based upon the intended use and descriptive information provided in this pre-market notification, the Osprey Medical AVERT System has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

Osprey Medical
C/O Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131478
Trade/Device Name: AVERT Contrast Modulation System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II
Product Code: DXT
Dated: June 26, 2013
Received: June 27, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. INDICATIONS FOR USE STATEMENT

510(k) Number: K131478

Device Name: AVERT Contrast Modulation System

Indications For Use:

The Osprey Medical AVERT Contrast Modulation System is intended to be used for the controlled infusion of radiopaque Iodixanol 270 mg/ml contrast media for angiographic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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